Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparision of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Protocol summary

Study aim
Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Design
This study is clinical trials and double blind.84 patients with Coronary Artery Bypass Graft Referring to Amiralmomenin Hospital in Arak.

Settings and conduct
This study is clinical trials and double blind.84 patients with Coronary Artery Bypass Graft Referring to Amiralmomenin Hospital in Arak.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with elective CABG; ASA class 2 and 3; Insensitivity to Amiodarone; performing surgery by a surgeon; duration of the surgery is 4 to 6 hours; all patients have normal creatinine Exclusion criteria: going on a cardio-pulmonary pump for 2 times during operation; all patients who die during surgery; Increase the duration of the operation for more than 6 hours; cardiomegaly and CHF; Cardiomyopathy History of cardiac arrest and CPR before surgery

Intervention groups
We inject 300 milligram Amiodarine bolus in 10-20 minute in first group after arterline. We inject 150 milligram Amiodarine and 2 gram vitamin C in second group after arterline.

Main outcome variables
Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N66**
Registration date: **2018-02-08, 1396/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-08, 1396/11/19**
Update count: **0**

Registration date
2018-02-08, 1396/11/19

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-11, 1396/08/20

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Public title
Comparision of prophylactic effect of amiodarone and

amiodarone with vitamin c on post CABG atrial fibrillation

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with elective CABG ASA class 2 and 3 Insensitivity to Amiodarone Performing surgery by a surgeon Duration of the surgery is 4 to 6 hours All patients have normal creatinine
Exclusion criteria:
Going on a cardio-pulmonary pump for 2 times during operation All patients who die during surgery Increase the duration of the operation for more than 6 hours Cardiomegaly and CHF Cardiomyopathy History of cardiac arrest and CPR before surgery
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization with random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2017-10-29, 1396/08/07
Ethics committee reference number
IR.ARAK.MU.REC.1396.150

Health conditions studied

1

Description of health condition studied
Coronary bypass graft
ICD-10 code
I25.70
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description
Arrhythmia atrial fibrillation and other arrhythmia
Timepoint
After treatment
Method of measurement
Count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We inject 300 milligram Amiodarine bolus in 10-20 minute in first group after arterline.
Category
Treatment - Drugs

2

Description
Intervention group: We inject 150 milligram Amiodarine and 2 gram vitamin C in second group after arterline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Dr Alireza Kamali
Street address

Amiralmomenin hospital, Sardasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Aliarash Anoshirvani
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
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anoshirvani@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Bijan Yazdi
Position
Assistant, anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Samira Yavari
Position
Student of medicine
Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Payambar Azam Complex, Basij square, Sardasht, Arak

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Alireza Kamali

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments